Product Performance and Substantial Equivalency
510k Summary

DEC 2 4 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023731

Submitter: Consolidated Technologies
4401 Freidrich Lane
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Austin, TX 78744-1832
Phone: (512) 445-5100
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Contact: Candice Betz **Preparation date:** October 31, 2002

Product name (trade & common):

Proprietary: QUICKCHECK LIQUID CHEMISTRY CONTROL (Assayed and Unassayed), Levels 1, 2 and 3

Common: N/A

Classification name:
Class I, Product code: JJY
21 CFR 862:1660: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Predicate device:
QUICKCHECK UNASSAYED CHEMISTRY CONTROL, Levels 1 and 2.
Consolidated Technologies, Inc. K-973469

Device description:
QUICKCHECK LIQUID CHEMISTRY CONTROL is designed to monitor the performance of test procedures that analyze a number of routine chemistry analytes as listed in the package insert.

This product will be offered as an assayed and unassayed control. In addition, the control is being expanded to three levels.

Intended use:
QUICKCHECK LIQUID CHEMISTRY CONTROL is a liquid human serum based assayed quality control material intended to monitor the performance of test procedures that analyze routine chemistry analytes as listed in the package insert.

Labeling/Packaging:
Consolidated Technologies is a contract manufacturer. The expected values listed on the package insert for QuickCheck Liquid Chemistry Control are target ranges developed for manufacturing purposes only. These expected values are based on the product having three distinct levels. As such, CTI will manufacture, at the request of a customer, either unassayed or assayed QuickCheck Chemistry Control product.

If the customer requests an unassayed product, the expected manufacturing targets for the product will be presented for reference and a certificate of analysis will accompany the final product for completion. The certificate of analysis will list the actual values obtained for analytes present in the control (see exhibit I for example)

If the customer requests an assayed control the package insert will list the analytes present in the control and the values obtained for those analytes on various test methods and/or instrumentation. The customer determines the test methods and instrumentation. The value assignment data (assayed) are provided to the customer to develop their own package insert. See exhibit II for an example of an assay sheet.

The customer is responsible for labeling and/or package insert for the finished device.

This product is offered to the customer in the following fill sizes:

5ml fill in a 7ml amber glass vial
4ml fill in a 7 ml amber glass vial
10ml fill in a 15ml amber glass vial
10ml fill in a 15 ml plastic dropper vial

Unlabeled vials in labeled flats
Labeled vials in flats
Labeled vials in Labeled kits

Consolidated Technologies is also a manufacturer and will sell this product as QuickCheck Liquid Chemistry Control, Level 1, 2, and 3. The package insert will list the analytes present in the control and the values obtained for those analytes on various test methods and/or instrumentation. The assay sheet included in this 510k is an example of potential methods used to assay the product. See Exhibit II, III, IV and V, for all labeling and package insert and example assay sheet.

QuickCheck Liquid Chemistry Control is sold in the following configurations:

5ml in a 7ml labeled vials
10ml in a 15ml labeled vials
The above kitted are 5 of each level to equal 15 vials or 15 vials of the same level
Package Insert

Product Performance and Substantial Equivalency
510(k) Summary (continued)

Comparative analysis:
The table below provides a summary of the technological characteristics between QUICKCHECK LIQUID CHEMISTRY CONTROL and the predicate device.

Device Characteristic	**Proposed Device QUICKCHECK LIQUID CHEMISTRY CONTROL**	**Predicate Device QUICKCHECK UNASSAYED CHEMISTRY CONTROL**
Intended use	Assayed quality control serum for monitoring performance of routine chemistry test procedures.	Uassayed quality control serum for monitoring performance of routine chemistry test procedures
Matrix	Human Serum	Human Serum
Form	Liquid, Frozen	Liquid, Frozen
Analytes	59 analytes of clinical significance that may be found in serum.	43 analytes of clinical significance that may be found in serum
Levels	Three (3) levels	Two (2) levels
Preservatives	Ciprofloxacin	Ciprofloxacin
Storage	-20°C	-20°C
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label

Conclusions:
The information provided in the pre-market notification demonstrates that QUICKCHECK LIQUID CHEMISTRY CONTROL (Assayed and Unassayed) is substantially equivalent to the predicate device, for which there is FDA clearance. This equivalence was demonstrated through comparison of intended uses and physical properties to a commercially available device. The information supplied in the pre-market notification provides reasonable assurance that QUICKCHECK LIQUID CHEMISTRY CONTROL is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 4 2002

Ms. Candice Bentz
Quality Manager
Consolidated Technologies, Inc.
4401 Freidrich Lane
Building 1, Suite 100
Austin, TX 78744

Re: k023731
Trade/Device Name: QuickCheck Liquid Chemistry Control (Assayed and Unassayed). Levels 1, 2, and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: October 31, 2002
Received: November 6, 2002

Dear Ms. Bentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS OF USE STATEMENT

510(k) number (if known): K023731

Device name:

QUICKCHECK LIQUID CHEMISTRY CONTROL (Assayed and Unassayed), Levels 1, 2 and 3

Indications for use:

QUICKCHECK LIQUID CHEMISTRY CONTROL, Levels 1, 2 and 3, is a liquid human serum based assayed quality control material intended to monitor the performance of clinical test procedures that analyze routine chemistry analytes as listed in this package insert.

Division Sign-Off)
Clinical Laboratory Device
510(k) Number K023731

prescription use ✓